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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/088,814 | 09/04/2002 | Andrew Austen Mortlock | ASZD-P01-599 | 2356 |
| 44992 | 7590 | 09/18/2006 | | |
| ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215 | | | | |
| EXAMINER | | | | |
| TRUONG, TAMTHOM NGO | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1624 | | | | |

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,814

Applicant(s)

MORTLOCK ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 27, 30 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 27, 30 and 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

NON-FINAL ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-31-06 has been entered.

Claims 1-19, 21-26, 28, 29 and 31-33 have been cancelled.

Claims 20, 27, 30 and 34-44 are pending.

Applicant's terminal disclaimer has overcome the previous rejection of Obviousness-type Double Patenting.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 20, 27, 30 and 34-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 20 and dependent thereon are rejected because claim 20 recites the limitation of "*ester or amide thereof*" which has indefinite metes and bounds. Although

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the specification cites examples of ester and amide, such a list is open-ended. It is not clear what other moieties could be ester or amide. Furthermore, many substituents are amide or ester (e.g., -NHZR⁶⁴, -X¹R¹⁵ when X¹ is -OCO-, -SO₂-, -NR¹⁶CO-, etc.) which makes it unclear if additional ester or amide is intended.

b. Claim 27 recites the step of "*if desired or necessary converting a group of R^{1'}, R^{2'}, R^{3'} or R^{4'} to a group of R¹, R², R³ and R⁴ respectively or to a different such group*" which has indefinite metes and bounds because it is not clear which group gets converted into which. Note, R^{1'}-R^{4'} are the equivalent of R¹-R⁴, thus, it is not clear why conversion would be necessary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

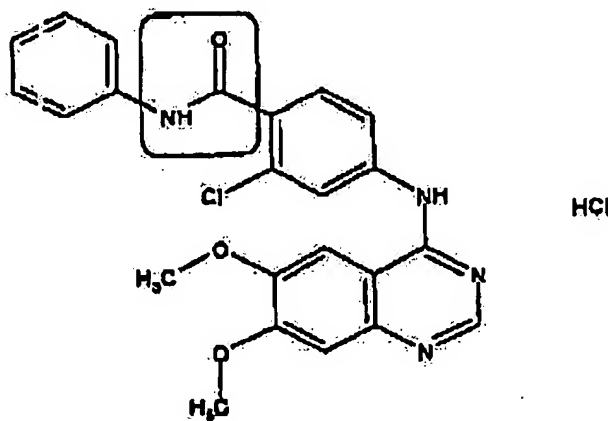
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 20, 27, 30 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brown et. al.** (WO 96/15118). On page 54, Example 11 lists the compound of **4-[3-chloro-4-(*N*-phenylcarbamoyl)aniline]-6,7-dimethoxyquinazoline hydrochloride salt** which has the following structure:

**Example 11**

The disclosed compound differs from the claimed formula (IIC) by having $-C(=O)NH-$... (or *carbamoyl*) attached to the anilino, and not $-NHC(=O)-$... (or *amido*) as in the side chain of formula (IIC). However, the disclosed formula I has variable X (at the position of the *carbamoyl*) which represents many divalent groups including $-CONR^3$ as well as $-NR^3CO-$ (see the definition of X on page 8). Thus, with such an equivalency teaching, the skilled chemist would have been motivated to modify the compound of Example 11 by replacing the –

C(=O)NH- group with $\text{-NR}^3\text{CO-}$. Note, the first proviso in claim 20 does not exclude obvious variants of the compound in Example 11 since the disclosed compound is substituted with Cl besides the carbamoyl group.

Regarding the process recited in the instant claim 27, the disclosed Example 1 provides starting materials that are analogous to the claimed formulae (VIII) and (IX'). Furthermore, it would have been within the level of the skilled chemist to follow the procedure in Example 1 using the appropriate starting materials.

The instant claims 34-43 recite substituents represented by R^1 and R^4 which fall within the scope of R^1 in WO'118 (see the definition of R^1 on page 7). Substituents represented by the instant R^7 and R^8 fall within the list of substituents on Q in WO'118 (see the definition of Q on page 7). Thus, with such a generic teaching, the skilled chemist would have been motivated to modify the compound of Example 11 by replacing the *6,7-dimethoxy* with other substituents represented by R^1 .

The instant claim 44 is also rendered obvious because the disclosed compound is used to treat various cancers including breast and colon cancers (see page 42, the 5th line from the bottom of the page).

Therefore, at the time the invention was made, it would have been obvious to make and use compounds of formula (IIC) in view of the generic and equivalency teaching above.

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References cited on PTO-892

4. The cited references show state of the art. Although they teach compounds of *4-anilino-quinazoline* substituted with -NHC(=O)- ..., the amido group is always at *meta* position.

No pending claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9-5-06


Tamthom N. Truong
Examiner
Art Unit 1624


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